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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/312,596	05/14/1999	LORNA W. ROLE	46839-B/JPW/	2831

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EXAMINER	
GUCKER, STEPHEN	

ART UNIT	PAPER NUMBER
1647	22

DATE MAILED: 06/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/312,596	Role et al.
Examiner	**Group Art Unit**
Stephen Gucker	1647

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

P riod for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☑ Responsive to communication(s) filed on 5/19/03.

☑ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☑ Claim(s) 1-19, 25-29, + 30-34 is/are pending in the application.

Of the above claim(s) 1-19 + 25-29 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☑ Claim(s) 30-34 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Ref rence(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other _____

Office Acti n Summary

Response to Amendment

1. The request filed on 5/19/03 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/312,596 is acceptable and a CPA has been established. An action on the CPA follows.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Any objections or rejections made in a previous Office Action that are not herein reinstated have been withdrawn.

4. Claims 30-34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods employing nARIA polypeptide sufficiently characterized by physical or chemical structure, such as by SEQ ID NO, does not reasonably provide enablement for methods employing "nARIA polypeptide". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The disclosure does not contain an adequate written description, examples, or guidance by which methods employing "nARIA polypeptide" characterized only by the verbal phrase "nARIA polypeptide" could be placed into the hands of the skilled artisan with a reasonable expectation of success without requiring undue experimentation for the following reasons. The scope of "nARIA polypeptide" is defined in the

specification as including "amino acid variants of nARIA which are prepared by introducing appropriate nucleotide changes into nARIA nucleic acid or by *in vitro* synthesis of the desired nARIA polypeptide. Such variants include, for example, deletions from, or insertions or substitutions of, residues within the amino acid sequence shown for human nARIA sequence. Any combination of deletions, insertion, and substitution can be made to arrive at the final construct, provided that the final construct possesses the desired characteristics" (page 17, line 35 to page 18, line 7). Because of the unpredictability of the protein arts (see Rudinger, especially page 6), the skilled artisan cannot make and use the broad genus of "nARIA polypeptide" recited in the method claims because such a genus encompasses an unlimited and thereby infinite plurality of amino acid substitutions, deletions, additions, or combinations thereof as compared with the working embodiments because the disclosure does not adequately describe, provide guidance, or give examples of all the critical amino acid residues that bestow upon the protein its "desired characteristics". The instant process claims encompass all types and manner of "nARIA polypeptide,"including synthetic muteins made by genetic engineering, every and all "nARIA polypeptide"from every animal species on earth, and every possible allelic variant of the foregoing, that are not envisioned or adequately described by the disclosure. The working embodiments of the specification are a minor portion of a very broad genus and do not teach or support the majority of the genus as a whole because such a broad and varied genus drawn solely to the biological functionality of the product used without regard or limitation to its chemical

structure cannot be adequately enabled from the few examples taught. See Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

Applicants arguments filed 8/30/02 and 2/25/03 concerning only 2 species being enabling for the entire infinite breadth of the instant genus are unpersuasive for the reasons set forth above.

5. Claims 30-34 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

The skilled artisan cannot envision the detailed chemical structure of the encompassed "nARIA polypeptide" used in the process claims and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of manufacturing or testing the claimed processes. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for making or

testing it. One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481, 1483. In Fiddes v. Baird, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision. (See page 1115.).

It is suggested that by limiting the claims to methods using the instant "nARIA polypeptide" described as a SEQ ID NO would obviate the grounds of this rejection.

Applicants arguments filed 8/30/02 and 2/25/03 concerning only 2 species being adequate written description for the entire infinite instant genus are unpersuasive for the reasons set forth above.

6. Claims 30-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is vague and unclear how "the agent" is supposed to be used in base claim 20 when it is recited as being absent in both steps (a) and (c).

7. Claims 30-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Goodearl et al. (US 5,602,096, "Goodearl"). Goodearl discloses glial growth factors (GGF) that possess nARIA activity in that they induce acetylcholine receptor synthesis by binding to the same receptor ($p185^{erbB2}$ or erbB2) as does "nARIA polypeptide" (abstract, column 5, line 36; column 16, line 65 to column 17, line 5; column 47, lines 5-17; and claims 1-2.). Goodearl also discloses competitive assays with glial growth factors in affinity chromatography (the receptor can be

bound to the affinity derivative by the ligand) and antibodies which meet the limitations of the claims (column 4, lines 63 to column 5, line 7; column 12, lines 19-67; column 8, lines 16-57). It is noted that the claims as presently written do not require the presence of an agent, but only a ligand (an ARIA or a GGF), a receptor, and an antibody.

8. Claims 30-34 are rejected under 35 U.S.C. 102(e) as being anticipated by Role (US 6,284,535 B1, "Role"). Role discloses the invention at column 16, line 61 to column 17, line 13. It is noted that the claims as presently written do not require the presence of an agent, but only a ligand (an ARIA or a GGF), a receptor, and an antibody.

9. Claims 30-34 are rejected under 35 U.S.C. 102(f) because some of the applicants did not invent the claimed subject matter. The invention is disclosed in its entirety and verbatim in the Role patent at column 16, line 61 to column 17, line 13. Compare page 35, line 29 to page 36, line 13 of the instant application with column 16, line 61 to column 17, line 13 of the Role patent. Lorna W. Role is listed as the sole inventor of US 6,284,535 B1. Therefore, applicants David Talmage and Jianxin Bao of the instant application are not co-inventors of the invention sought to be patented in the instant application. It is noted that the claims as presently written do not require the presence of an agent, but only a ligand (an ARIA or a GGF), a receptor, and an antibody.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 30-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodearl in view of Role. The teachings of Goodearl are as set forth in ¶7 above. Goodearl does not teach the affinity complex comprising an nARIA receptor bound to an affinity derivative or specific affinity derivatives. Role teaches the affinity complex comprising an nARIA receptor bound to an affinity derivative or specific affinity derivatives at column 16, line 61 to column 17, line 13. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the methods of Goodearl with the methods of Role because both US patents have a common nexus of teaching the inducement of ACh receptors by the use of nARIA or GGF (which are alternately spliced from the same gene and act on the same receptor), both patents disclose competitive binding assays and antibodies using nARIA or GGF, and the use of affinity derivatives such as sepharose is common practice in the art for competitive binding assays such as immunoassays and ELISAs because of the advantage of having a ligand or receptor reagent bound to an affinity derivative such as sepharose for the convenience of making said assay amenable to being used, sold, or marketed in kit form.

Applicants arguments filed 8/30/02 and 2/25/03 concerning the references not teaching erbB2 receptors are unpersuasive. Goodearl and Role teach erbB2 receptors as previously noted.

12. No claim is allowed.

13. This is a CPA of applicant's earlier Application No. 09/312,596. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (703) 308-6571. The examiner

can normally be reached on Monday to Friday from 0930 to 1800. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is currently (703) 308-4242, but Applicant should confirm this by phoning the Examiner before faxing.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SG

Stephen Gucker

June 6, 2003

Gary L. Kunz

GARY KUNZ
SUPERVISORY PATENT EXAMINER
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